Thiamethoxam Receipt of Application
for Emergency Exemption
Solicitation of Public Comment
OPP # 181077

NUM	DATE	LNAME	AFFIL	TITLE	PAGES	DOC TYPE
0001	05/19/00	Schaible	EPA	Thiamethoxam Receipt of Application for Emergency Exemption, Solicitation of Public Comment (FR Notice)	4	A
0002	04/17/00	McCarty	State of Miss. Dept. of Agri & Commerce	Letter to Ms. Meredith Laws from Robert McCarty	1	A
0003	04/17/00	McCarty	State of Miss. Dept. of Agri. & Commerce	Letter to Lester Spell from Robert McCarty	1	A
0004	04/17/00	McCarty	State of Miss. Dept. of Agri. & Commerce	Letter to Gov. Ronnie Musgrove from Robert McCarty	1	A
0005	04/17/00	McCarty	State of Miss. Dept. of Agri. & Commerce	Application for a Specific Exemption for Use of Centric (Thiamethoxam) to Control Cotton Aphids in Cotton in Mississippi	16	A
0006	03/13/00	Novaris	Novaris	Copy of Draft Label for Centric	10	A
0007	05/30/00	Cain	Bayer Corp.	Notice of Specific Exemption Request for Use of Centric on Cotton	5	A
0008	06/05/00	Koch	Bayer AG	Notice of Specific Exemption	4	A

Request for use
of Centric on
Cotton

Thiamethoxam Receipt of Application
for Emergency Exemption
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EPA United States Environmental Protection Agency

Federal Register Document

Related Material

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[Notices]
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From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr19my00-59]

ENVIRONMENTAL PROTECTION AGENCY

[OPP-181077; FRL-6559-4]

Thiamethoxam; Receipt of Application for Emergency Exemption, Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received a specific exemption request from the Mississippi Department of Agriculture and Commerce to use the pesticide thiamethoxam (CAS No. 153719-23-4) to treat up to 1,000,000 acres of cotton to control cotton aphids. The Applicant proposes the use of a new chemical which has not been registered by the EPA; this would also be a first food use of this pesticide. EPA is soliciting public comment before making the decision whether or not to grant the exemption.

DATES: Comments, identified by docket control number OPP-181077, must be received on or before June 5, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-181077 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: Stephen Schaible, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703 308-9362; fax number: 703

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308-5433; e-mail address: schaible.stephen@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you petition EPA for emergency exemption under section 18 of FIFRA. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
State government	9241	State agencies that petition EPA for section 18 pesticide exemption

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. Other types of entities not listed in the table in this unit could also be regulated. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action applies to certain entities. To determine whether you or your business is affected by this action, you should carefully examine the applicability provisions in this document. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. Electronically. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ``Laws and Regulations'' and then look up the entry for this document under the ``Federal Register--Environmental Documents.'' You can also go directly to the Federal Register listings at http://www.epa.gov/fedrgstr/.

2. In person. The Agency has established an official record for this action under docket control number OPP-181077. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-181077 in the subject line on the first page of your response.

1. By mail. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. In person or by courier. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. Electronically. You may submit your comments electronically by e-mail to: ``opp-docket@epa.gov,'' or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPP-181077. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI that I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of

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the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under FOR FURTHER INFORMATION CONTACT.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the proposed rule or collection activity.

7. Make sure to submit your comments by the deadline in this document.

8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and Federal Register citation.

II. What Action is the Agency Taking?

Under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136p), at the discretion of the Administrator, a Federal or State agency may be exempted from any provision of FIFRA if the Administrator determines that emergency conditions exist which require the exemption. The Mississippi Department of Agriculture and Commerce has requested the Administrator to issue a specific exemption for the use of thiamethoxam on cotton to control cotton aphids. Information in accordance with 40 CFR part 166 was submitted as part of this request.

As part of this request, the Applicant asserts that cotton aphid has developed resistance to most currently labeled and recommended insecticides in Mississippi. It is claimed that laboratory assays, field experiments, and field experience indicate that insecticides currently recommended for cotton aphid control are variable in effectiveness to the extent that agricultural consultants and cotton producers consider them to be unreliable. Studies suggest aphids may be initially controlled with registered alternatives such as dicrotophos, endosulfan, methomyl and imidacloprid, but that populations resurge rapidly following application. Aphids are naturally controlled by the fungal disease Neozygites fresenii once aphid populations have reached high infestation levels, but it is often difficult to predict when disease epizootics will occur. Recently, participation in the Boll Weevil Eradication Program has resulted in greater risk of yield threatening outbreaks of cotton aphids. Because of the intensive use of malathion for eradication of the boll weevil, the early years of eradication effort are considered to be years of increased risk of secondary pest outbreak; survey data collected in Mississippi in 1998 support this claim. The Applicant estimates that in the event of a severe aphid outbreak yield losses as high as 50 lbs per acre could be sustained using currently available products. It is claimed that yield losses using thiamethoxam under similar conditions would be around 10 lbs. per acre. These yield losses would result in a projected difference in net returns to the producer of $25 per acre, in the event of heavy, sustained aphid infestations.

The Applicant proposes to make no more than two applications of the product Centric, containing 25% of the active ingredient thiamethoxam, to a maximum of 1,000,000 acres of cotton in Mississippi, between June 15 and September 15, 2000; a maximum of 94,000 lbs. a.i. (375,000 lbs. of product) would be used under this exemption.

This notice does not constitute a decision by EPA on the application itself. The regulations governing section 18 of FIFRA require publication of a notice of receipt of an application for a specific exemption proposing ``use of a new chemical (i.e., an active ingredient) which has not been registered by the EPA'', and also `` a first food use of a chemical.'' The notice provides an opportunity for public comment on the application.

The Agency, will review and consider all comments received during the comment period in determining whether to issue the emergency exemption requested by the Mississippi Department of Agriculture and Commerce.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: May 10, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 00-12650 Filed 5-18-00; 8:45 am]

BILLING CODE 6560-50-F

02/OPP#181077

THE STATE OF MISSISSIPPI
DEPARTMENT OF AGRICULTURE AND COMMERCE
BUREAU OF PLANT INDUSTRY
P.O. BOX 5207
Mississippi State, Mississippi 39762-5207
Telephone (601) 325-3390; FAX (601) 325-8397

LESTER SPELL JR., D.V.M.
COMMISSIONER

ROBERT MCCARTY
DIRECTOR AND
STATE ENTOMOLOGIST

April 17, 2000

IP

Meredith Laws, Team Leader
Emergency Response Team, (7505C)
U.S. EPA/Office of Pesticide Programs
Document Processing Desk
Crystal Mall 2 – 2nd Floor
1921 Jefferson Davis Hwy.
Arlington, VA 22202

Dear Mrs. Laws:

Enclosed is a request for a specific exemption to use the product Centric insecticide for the control of cotton aphid in cotton under emergency conditions in 2000.

If you have any questions, please feel free to give me a call.

Sincerely,

Robert McCarty
Director

RM/hl

Enclosure

03/OPP#181077

THE STATE OF MISSISSIPPI
DEPARTMENT OF AGRICULTURE AND COMMERCE
BUREAU OF PLANT INDUSTRY
P.O. BOX 5207
Mississippi State, Mississippi 39762-5207
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LESTER SPELL JR., D.V.M.
COMMISSIONER

ROBERT MCCARTY
DIRECTOR AND
STATE ENTOMOLOGIST

April 17, 2000

(1P)

Commissioner Lester Spell
Mississippi Department of Agriculture and Commerce
P. O. Box 1609
Jackson, MS 39205

Dear Commissioner Spell:

Enclosed for your information is a copy of an application to the Environmental Protection Agency for an emergency exemption to use the product Centric for the control of cotton aphid in cotton under emergency conditions as provided for under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

If you have any questions, please feel free to give me a call.

Sincerely,

Robert McCarty
Director

RM/hl

Enclosure

04/OPP#181077

THE STATE OF MISSISSIPPI
DEPARTMENT OF AGRICULTURE AND COMMERCE
BUREAU OF PLANT INDUSTRY
P.O. BOX 5207
Mississippi State, Mississippi 39762-5207
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LESTER SPELL JR., D.V.M.
COMMISSIONER

ROBERT MCCARTY
DIRECTOR AND
STATE ENTOMOLOGIST

(1P)

April 17, 2000

Governor Ronnie Musgrove
New Capitol Building
Jackson, MS 39205

Dear Governor Musgrove:

Enclosed for your information is a copy of an application to the Environmental Protection Agency for an emergency exemption to use the product Centric for the control of cotton aphid in cotton under emergency conditions as provided for under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

If you have any questions, please feel free to give me a call.

Sincerely,

Robert McCarty
Director

RM/hl

Enclosure

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A

APPLICATION FOR SPECIFIC EXEMPTION

IN ACCORDANCE WITH SECTION 18

OF THE AMENDED FIFRA

16PP

I. STATE AGENCY RESPONSIBLE FOR THE EMERGENCY PROGRAM.

A. Mississippi Department of Agriculture & Commerce

Bureau of Plant Industry

P. O. Box 5207

Mississippi State, MS 39762

B. Cooperating Agency

Mississippi Cooperative Extension Service

Mississippi State University

Mississippi State, MS 39762

C. Knowledgeable experts to contact in case any questions arise.

CONTACT	QUALIFIED EXPERT
Mr. Robert McCarty	Dr. Blake Layton
Bureau of Plant Industry	Dept. of Entomology & Plant Pathology
P. O. Box 5207	Box 9775
MS State, MS 39762	MS State, MS 39762
Phone # (601) 325-3390	Phone # (601) 325-2085

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II. DISCUSSION OF EVENTS WHICH BROUGHT ABOUT THE EMERGENCY

In recent years aphids have become more important as a pest of Mississippi cotton. Infestations have begun to develop earlier in the production season and consistent control has become very difficult to achieve with currently available materials due to high levels of insecticide resistance.

Cotton aphid, Aphid gossypii, has developed resistance to most currently labeled and recommended insecticides in Mississippi. O'Brien et al. (1990) found significant levels of tolerance to Lorsban, Thiodan, Metasystox-R and Bidrin in field populations collected in 1989 at Stoneville, MS. Cotton aphid control experiments in the Mississippi Delta have shown lack of control by most recommended insecticides (Harris et al. 1993, 1994, 1995). These workers found Bidrin and Provado to be the most effective currently recommended aphid control products. However, Reed et al. (1995) reported cotton aphid control by Bidrin (.25 lb ai/acre) was highly variable and ranged from 85% to 25% in various tests between 1987 and 1993 in the Mississippi Delta. Such variability in performance of Bidrin and other aphicides used at different locations and times has also been reported by consultants in Mississippi (Sartor 1995, Tate 1995. personal communications).

Laboratory assays, field experiments, and field experience indicate that insecticides currently recommended for cotton aphid control are variable in effectiveness to the extent that agricultural consultants and cotton producers consider them to be unreliable.

Although the naturally occurring fungal disease, Neozygites fresenii, usually provides natural control of aphid populations once they build to and maintain high

infestation levels for several days, it is often difficult to predict when disease epizootics will occur. Research conducted within the state has indicated that the effect of aphids on yields is quite variable, but losses of approximately 125 to 220 lbs of lint per acre have been measured in some cases (Weathersbee and Hardee, 1994; Harris, et. al. 1992; Layton et al, 1995).

In 1995, aphid infestations began appearing on seedling cotton and treatable populations were present in some fields (in excess of 600 aphids per leaf in one field) by the second week of June. This was approximately 2 weeks earlier than treatable infestations normally appear. Although results of an efficacy trial conducted against these early populations of aphids showed that most recommended products gave substantial levels of initial control, populations rebounded quickly following treatment (Layton et al, 1995). Numerous producers and consultants reported field control failures with recommended products and requested that alternative products be made available if possible.

Research at Stoneville, MS from 1986 to 1993 has shown that cotton aphid infestations can cause yield losses in some situations. Andrews and Kitten (1989) reported studies conducted in the Mississippi Delta over a 3-year period and 5 field experiments where different levels of aphid infestations were achieved with different use patterns of dimethoate insecticide. These researchers found a negative impact on yield as aphid infestation increased where infestation was expressed in "aphid days" (aphid days = an accumulation of aphids/leaf/day), and they developed a regression equation from the data with which aphid infestations effect on cotton yield can be estimated. Harris et al. (1992) used aphid infestation and yield data from insecticide efficacy field experiments to validate the Andrew and Kitten (1989) regression equation. They reported a "consistent pattern of a

negative relationship between cotton aphid infestation expressed in 'aphid days' and seed cotton yield " similar to that predicted by the Andrews and Kitten (1989) equation. A later study reported by Harris and Furr (1994) showed that the Andrews and Kitten (1989) equation predicted a yield difference between aphicide treated DES 119 cotton of 90 lbs seed cotton/seed compared to an actual loss of 116 lbs/acre. The predicted loss in Deltapine 51 cotton was 121 lbs of seed cotton/acre and the actual loss was 138 lbs/acre. The average lint loss of the two varieties was calculated to be 45 lbs/acre based on 35% lint turnout. The two varieties sustained an average of 402 aphid days with peak infestation at 35 aphids/leaf.

These studies indicated that cotton aphid infestations can cause significant yield losses in cotton, that the Andrews and Kitten (1989) regression equations is a reliable predictor of cotton aphid infestations effects on yield, and that in one specific case an infestation that peaked at 35 aphids/leaf caused a 45 lb/acre lint yield loss. Since a 45 lb/acre lint yield loss @ $.70/lb is a gross revenue loss of $31.50 to a cotton producer, the treatment threshold for insecticide intervention against cotton aphids should not be higher that 35 aphids/leaf.

One recent development that greatly increases the risks of yield threatening outbreaks of cotton aphids is the involvement of much of Mississippi in a Boll Weevil Eradication Program. The Hill Region of Mississippi (approximately 365,000 acres) began eradication efforts in the fall of 1997 (Layton, et. Al., 1999) and was followed by the South Delta Region (approximately 126,000 acres), which began eradication efforts in the fall of 1998. The North Delta Region initiated eradication efforts in the fall of 1999 on over 500,000 acres of cotton. Because of the intensive use of ULV malathion for eradication of the boll weevil,

the early years of an eradication effort are considered to be years of increased risks of secondary pest outbreaks.

During 1998, a season long survey comparing aphid populations from fields located in the active boll weevil eradication program in the Hill region to those in fields located outside the boll weevil eradication program clearly demonstrated this flaring of cotton aphids. Nine out of nine fields located inside the eradication program either exceeded populations of 100 aphids per leaf or were treated with an aphicide before this population level was reached. Only one out of seven survey fields located in the non-eradication area reached populations in excess of 100 aphids per leaf, and no survey fields in this area were treated for aphids (Layton & Long, 1999). This flaring of cotton aphids was also observed during the late summer of 1997, following initiation of the boll weevil eradication effort. It is noteworthy that, based on the Cotton Insect Losses Estimate for 1998, aphids were ranked as the second most damaging cotton pest in the Hill region (Bollworm/Tobacco Budworm were ranked first) and aphids were estimated to have caused 1.8% yield loss. Both yield losses and aphid related control costs would have been much greater in the absence of the Section 18 Emergency Exemption allowing use of Furadan in 1998, as well as 1999.

III. DESCRIPTION OF THE PESTICIDE:

Common Chemical Name (Active Ingredient): Thiamethoxam

Trade Name: Centric

EPA Reg. No.:

Formulation: Water-dispersible granule

% Active Ingredient: 25.0%

Manufacturer: Novartis

IV. DESCRIPTION OF THE PROPOSED USE:

A. Location of the sites to be treated.

The intended area of application is cotton fields within the State of Mississippi.

B. Method of Application

Centric may be applied using ground or aerial application equipment in a minimum of 5 gallons per acre total volume by air or in sufficient water volume to provide thorough and uniform coverage, by ground application equipment.

C. Rate of Application

Centric shall be applied at the rate of 3.0 oz/A or .047 lbs ai/A. The number of applications of Centric shall be limited to 2 per acre.

D. Acreage to be treated

A maximum of 1,000,000 acres may be treated.

E. Quantity of Pesticide

At the maximum proposed rate of 0.047 lb ai/A, and a maximum 2 applications, a total of 94,000 lbs. ai (375,000 lbs) of Centric may be used.

F. Use Season

June 15 through September 15.

V. ALTERNATIVE METHODS OF CONTROL

Materials currently recommended in the Mississippi Cotton Insect Control Guide for control of cotton aphid include: dicrotophos (Bidrin), endosulfan (Phaser and

Thiodan), methomyl (Lannate) and imidacloprid (Provado). Results of a small plot efficacy trial conducted in June of 1995 (Layton, 1995) showed that all of these recommended products provided substantial reduction of aphid populations, with Bidrin, Lannate, and Provado providing the highest levels of control. However populations resurged rapidly and exceeded 100 aphids per leaf by 9 days post-treatment. Numerous reports received from producers and consultants in 1995 indicated inconsistent control with all recommended products in actual field use and populations rebounding rapidly following treatment.

Table 1 provides a brief summary of aphid efficacy trials conducted in Mississippi during 1993, 1994 and 1995. Copies of more detailed reports are included in Section 5.

Table 1: Summary of Aphid Efficacy Trials Conducted in Mississippi 1993, 1994 and 1995

Year	Investigator	Treatment	Aphid Populations		
			# Aphids/10 Leaves		
			4DAT	8DAT	
1993	Layton - MS	Untreated	824	663	
		Bidrin 0.4	262	353	
		MSR 0.33	641	799	
		Lannate 0.24	566	881	
			Avg # Aphids/Sq. Inch		
			3DAT	7DAT	4DAT
1994	Elzen- MS	Untreated	20.3	10.0	4.3
		Furadan 0.25	0.5	0.1	0.2
		Bidrin 0.4	0.8	0.1	0.2
		Methyl P. + Thiodan 0.5 + 0.75	0.6	0.3	0.6
			Avg Aphids/Leaf (Mid-Leaf)		
			7DAT	13DAT	
1994	Harris - MS	Untreated	106	104	
		Furadan 0.25	12	17	
		Bidrin 0.4	13	17	
		Methyl P. + Thiodan 0.5 + 0.75	36	18	
			Avg Aphids/Leaf (Mid-Leaf)		
			7DAT	13DAT	
1994	Harris - MS	Untreated	27.2	87.1	
		Bidrin 0.3	10.3	34.0	
		Monitor 0.25	32.7	84.2	
		Admire 0.22	15.8	49.8	

Year	Investigator	Treatment (lb ai/A)	Aphid Populations	
			Avg Aphids/Leaf	
			2DAT	5DAT
1995	Layton - MS	Untreated	200 +*	200 +*
		Bidrin 0.4	19	58
		Lannate 0.45	31	89
		Provado 0.047	41	101
		MSR 0.33	45	118
		Thiodan 0.75	127	185

Sampling stopped counting at 200 aphids per leaf--actual infestations were in excess of 600 per leaf.

			Avg # Aphids/Sq. Inch	
			3DAT	11DAT
1995	Harris - MS (Stoneville)	Untreated	140	38
		Provado 0.045+ Kinetic	30	18
		Bidrin 0.4	8	15
		Furadan 0.25	4	10
		Furadan 0.5	5	10

			Avg # Aphids/Sq. Inch
			5DAT
1995	Harris - Ms (Tribbett)	Untreated	158
		Bidrin 0.3	2
		Provado 0.047	4
		Karate 0.034 + Bidrin 0.3	2

			Avg. Aphids/Leaf
			2DAT
1995	Reed - MS	Untreated	20
		Furadan 0.33	2.5
		Furadan 0.5	3.0
		Thiodan 0.7	11.0
		Provado 0.047	3.1
		Lannate 0.45	1.6
		Bidrin 0.2	4.6

There are many naturally occurring biological control agents that also aid in suppressing aphid infestations. Several predatory insects feed on aphids and one particular species of parasitic wasp, often parasitizes a very high portion of the population. However the most important biological control is provided by the Neozygites fungus which typically develops once aphid populations reach and maintain high levels. Once an epizootic develops in a population, control is quite rapid and effective. Such outbreaks historically have developed in Mississippi cotton aphids around July 10-25. In 1995, this fungal outbreak occurred somewhat earlier than normal, beginning approximately July 4.

VI. EFFICACY OF PROPOSED USE:

Table 1 summarizes the results of 6 trials involving the use of thiamethoxam (Centric) against cotton aphids. Currently there are very few available trial reports by public sector entomologists on the efficacy of thiamethoxam applied as a foliar spray for control of cotton aphids. The trials reported in Table 1 were all conducted in 1999 and were conducted in Mississippi or neighboring states. The limited data that is available indicate that Centric is effective as a foliar treatment against cotton aphids and, when used at the 0.047 lbs ai/acre rate, has efficacy that is similar to that of Furadan (carbofuran).

VII. DISCUSSION OF RESIDUES FOR FOOD USES:

On December 4, 1998, Novartis submitted a petition to EPA (PP No. 9F5051) to establish tolerances for thiamethoxam in cotton. This petition includes all the data required for the agency to set appropriate tolerances for thiamethoxam and its metabolites in cotton commodities.

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VIII. **DISCUSSION OF RISK INFORMATION**:

Novartis has submitted to the agency data to support the safety finding for this use. A copy of Reduced-Risk Rational Document is attached.

IX. **NOTIFICATION OF REGISTRANT**

Novartis, the manufacturer of Centric has been notified that a Section 18 Emergency Exemption is being requested, and is cooperating by providing necessary information to prepare this application.

X. **DESCRIPTION OF THE PROPOSED ENFORCEMENT PROGRAM**

Pesticides and pesticide applicators are regulated in Mississippi under five separate state laws by the Mississippi Department of Agriculture and Commerce, Bureau of Plant Industry. The title of the laws with the appropriate code sections are listed below with a statement of purpose of each.

A. Regulation of Professional Services

Mississippi Code 1972, Title 69, Chapter 19, Sections 69-19-1 through 69-19-11 Section 69-19-1: "The Commissioner of Agriculture and Commerce shall have the power to make rules and regulations to govern the qualifications and the practicing of persons engaged in the professional services herein defined and to prevent further fraudulent practices in the said professional services."

B. Agricultural Aviation Licensing Law of 1966

Mississippi Code 1972, Title 69, Chapter 21, Article 3, Sections 69-21-101 through 60-21-125 Section 69-21-103: Declaration of Purpose - "The purpose of this article is to supervise and regulate for the public good all commercial agricultural aerial application within the State of Mississippi and to establish and promote a close working relationship between agricultural aerial applicators and the Commissioner of

Agriculture and Commerce by the licensing of all persons engaged in the aerial application of pesticides, poisons, seeds, and chemicals and the registration of all such commercial agricultural aircraft."

C. Mississippi Pesticide Application Act of 1975.

Mississippi Code 1972, Title 69, Chapter 23, Sections 69-23-101 through 69-23-133 Section 69-23-105: Declaration of Purpose - "The purpose of Section 69-23-101 to 69-23-133 is to provide a means for the state certification of applicators of restricted use pesticides required under the Federal Insecticide, Fungicide and Rodenticide Act, and to regulate in the public interest the use and application of such pesticides, except as such application is regulated under Section 69-191-1 through 69-19-11, 69-21-1 through 69-21-27, and 69-21-101 through 69-21-125, and to designate the Bureau of Plant Industry, Mississippi Department of Agriculture and Commerce, as the agency responsible for administering a plan for certification of applicators of restricted-use pesticides and to cooperate with the United States Environmental Protection Agency as provided for in the Federal Insecticide, Fungicide and Rodenticide Act, and for the other purposes."

D. Mississippi Pesticide Law of 1975

Mississippi Code 1972, Title 69, Chapter 21, Section 69-23-1 through 69-23-27 A specific purpose section is not set forth in the act; however, the purpose can be stated as follows: "The Pesticide Law provides for control of pesticides sold and distributed in the state through labeling and registration requirements and licensing requirements for pesticide dealers."

E. Control and supervision of the program will be as follows:

The Mississippi Department of Agriculture and Commerce/Bureau of Plant Industry will monitor the application of the exempted pesticide as

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needed to determine that the provisions of the specific exemption are being followed.

Applications will be limited to threshold level infestations as described in the Cotton Insect Control Guide.

XI. ANTICIPATED ECONOMIC LOSS

Table 2: Estimated yearly yield losses to cotton aphids, Mississippi Delta and Hills.

Yield Losses and Cost of Control Estimated for Cotton Aphid in Mississippi Delta				
Year	**% Loss**	**No. App**	**Cost of 1 App**	**Est. Control Cost**
1989	1.48	2.1	6.52	13.69
1990	1.80	1.0	7.65	7.65
1991	0.01	1.4	8.5	11.9
1992	0.07	0.7	9.5	6.65
1993	1.05	0.9	6.73	6.06
1994	0.71	0.6	5.04	3.02
1995	1.71	1.3	7.06	9.18
1996	0.79	0.49	6.33	3.10
1997	0.73	0.28	8.33	2.35
1998	0.42	0.39	8.50	2.71
1999	0.4	1.01	7.25	7.33
Mean	0.98	1.14	7.28	8.30

Yield Losses and Cost of Control Estimates for Cotton Aphid Mississippi Hills				
Year	**% Loss**	**No. App**	**Cost of 1 App**	**Est. Control Cost**
1989	0.61	1.0	4.43	4.43
1990	0.82	0.7	4.43	3.10
1991	0.01	0.8	8.50	6.80
1992	0.02	0.4	7.00	2.80
1993	0.52	0.5	7.20	3.60
1994	0.05	0.2	5.49	1.10
1995	0.71	0.3	6.25	1.88
1996	0.43	0.20	7.67	1.53
1997	0.81	0.39	7.50	2.91
1998	1.8	0.74	8.50	6.31
1999	0.4	0.15	7.20	1.08
Mean	0.39	0.56	6.19	3.38

The attached table shows estimated yield losses to cotton aphid for both the Hill and Delta areas of Mississippi since 1989. Losses range from 0.01% to 1.8% and costs of control range from $1.10 per acre to $13.69 per acre. However research has shown that aphids are capable of causing up to 125 to 220 lbs of lint loss under certain conditions.

A. Historical Net and Gross Revenues for Cotton in Mississippi

Year	Yield Per Acre (lb)	Price Per Pound ($)	Gross Revenue ($)	Cost Per Acre ($)	Net Revenue ($)
1995	622	0.7340	456.55	492.06	-35.51
1996	819	0.6800	556.92	471.34	85.58
1997	901	0.6490	584.75	489.48	95.27
1998	737	0.6000	442.20	547.11	-104.91
1999	708	0.5235	370.64	537.09	-166.45
MEAN	**757**	**0.6373**	**483.21**	**507.42**	**-25.20**

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B. Estimated net and gross revenues without the use of the proposed pesticide. (but with the next best alternative)

It is estimated that, in the event of a severe, sustained uncontrolled aphid outbreak, lint losses of approximately 100 lbs per acre may be sustained on as much as 20% of the acreage. This is approximately 2.74% yield loss for the state as a whole (100 lbs lint loss/ average yield of 757 lbs = 13.2% yield loss x 0.2 = 2.64%). However, it must be stressed that a yield loss of 100 lb. lint on 20% of the acreage would be quite damaging to those individual producers who were affected. Although available materials provide some control of aphids it is estimated that yield losses as high as 50 lbs per acre could be sustained even with 2 applications of currently available products.

Light infestations should be manageable with currently available materials and should not affect yields. Gross returns for heavy infestations can be calculated by reducing the five-year average yield of 757 pounds per acre by 50 lbs to equal 707 pounds per acre. Multiply this by the five-year average price of $0.637 to get gross returns of $450 per acre. Net returns are calculated by subtracting the average cost per acre ($507) from the gross returns ($450 - $507) or -$57.

C. Estimated net and gross revenues with the use of the proposed pesticide Centric

For light infestations assume no yield loss and no use of proposed product. For heavy infestations assume a 10 lb. yield loss or 757 lbs/ac - 10 = 747 lbs/ac x $0.637 = $476 gross returns and $476 - $508 = -$32. Thus the projected difference in net returns to the producer as a result of having this product available for use in the event of heavy, sustained uncontrollable aphid infestations is $25 per acre. However, it must be stressed that extremely heavy or prolonged infestations are capable of causing much greater losses, particularly if severe drought or other plant stress accompanies the aphid infestations.

Table 1: Summary of Trials involving Centric (Thiamethoxam) against cotton aphids in Cotton

Year	Location (investigator)	no. Apps.	Assessment Timing	Compound	Rate lb ai/A	% Control*	Type test
1999	Winnsboro, LA. (Leonard, LSU)	1	7DAT1	Provado 1.6 F Centric 25 WP** Capture 2 EC Fulfill 50 WG Furadan 4F	0.047 0.047 0.05 0.084 0.25	56 76 23 75 82	Rep. Small plot
1999	Stoneville, MS (Ngo, Novartis)	1	4DAT1	Fulfill 50 WG Centric 25WG ** Provado 1.6 F	0.085 0.047 0.045	88 98 93	Rep. Small plot
1999	Winnsboro, LA. (Leonard, LSU)	1	8DAT1	Centric 25WP ** by air Centric 25 WP** by ground Furadan 4F by ground	0.047 0.047 0.25	72 60 63	Rep. Large plot
1999	Stoneville, MS (Ngo, Novartis)	1	6DAT1	Centric 25WP ** Centric 25 WP** Fulfill 50 WG Furadan 4F	0.023 0.047 0.085 0.25	97 99 96 99	Rep. Small plot
1999	Arkansas (Moore, Novartis)	1	4DAT1	Centric 25WP ** Centric 25 WP** Fulfill 50 WG Furadan 4F	0.023 0.047 0.085 0.25	90 98 79 97	Rep. Small plot
1999	Winnsboro, LA. (Leonard, LSU)	1	2DAT1	Centric 25WP ** Centric 25 WP** Capture 2 EC Fulfill 50 WG Furadan 4F	0.023 0.047 0.05 0.085 0.25	98 98 70 88 96	Rep. Small plot

* % Control = [{(No. Insects in untreated Ck -No. in treated plot)/No. In untreated Ck} x 100]
** Ai was Thiamethoxam

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Section 18 Emergency Exemption

THIS PRODUCT FOR USE ONLY UNDER AN APPROVED SECTION 18 EMERGENCY EXEMPTION FOR USE ON COTTON IN MISSISSIPPI. CONTACT YOUR STATE DEPARTMENT OF AGRICULTURE OR STATE AGENCY RESPONSIBLE FOR PESTICIDE REGULATION TO DETERMINE IF A SECTION 18 IS IN EFFECT.

CentricTM

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For control of certain insect pests infesting cotton.

Active Ingredient:	
Thiamethoxam (CAS No. 153719-23-4):	25.0%
Other Ingredients:	15.3%
Cornstarch.	59.7%
Total:	100.0%

Centric is a water-dispersible granule.

EPA Reg. 100-

EPA Est. (To be Assigned)

KEEP OUT OF REACH OF CHILDREN.

CAUTION

See additional precautionary statements and directions for use on container label.

U.S. Standard Measure

NCP

1810

DIRECTIONS FOR USE AND CONDITIONS OF SALE AND WARRANTY

IMPORTANT: Read the entire **Directions for Use** and the **Conditions of Sale and Warranty** before using this product. If terms are not acceptable, return the unopened product container at once.

CONDITIONS OF SALES AND WARRANTY

The **Directions for Use** of this product reflect the opinion of experts based on laboratory and field trials. The directions are believed to be reliable and should be followed carefully. However, it is impossible to eliminate all risks inherently associated with use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Novartis Crop Protection, Inc. or the Seller. All such risks shall be assumed by the Buyer.

Novartis warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the **Directions for Use** subject to the inherent risks referred to above. **Novartis makes no other express or implied warranty of Fitness or Merchantability or any other express or implied warranty. In no case shall Novartis or the Seller be liable for consequential, special, or indirect damages resulting from the use or handling of this product.** Novartis and the Seller offer this product, and the Buyer and user accept it, subject to the foregoing **Conditions of Sale and Warranty**, which may be varied only by agreement in writing signed by a duly authorized representative of Novartis.

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DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Waterproof gloves
- Shoes plus socks

FAILURE TO FOLLOW DIRECTIONS AND PRECAUTIONS ON THIS LABEL MAY RESULT IN CROP INJURY, POOR INSECT CONTROL, AND/OR ILLEGAL RESIDUES.

3810

General Information

Centric controls sucking and chewing insects through contact and ingestion on many crops.

For best performance, always follow these directions:

- Centric should be applied when insect pest populations begin to build, but before populations reach economically damaging levels. Economic thresholds for pests controlled by Centric may be available from your local agricultural authorities.

- Centric is a selective insecticide that should not adversely impact beneficial arthropods and its use is compatible with integrated pest management programs. However, Centric is toxic to bees exposed to direct treatment or to residue on blooming crops and weeds. Do not apply Centric or allow it to drift onto blooming plants if bees are visiting the treated area.

- Centric is rapidly taken up into foliage after application. However, thorough spray coverage is essential for optimal performance. Apply Centric in sufficient water to ensure good coverage. See specific application information in the "Remarks" section of this label. The use of higher water volumes will generally result in better coverage, especially under adverse conditions (e.g. hot, dry) or where a dense plant canopy exists. The use of a spray adjuvant may improve spray coverage but is not required.

- Centric is rainfast once dried on treated plant parts.

- Centric has a wide margin of plant safety when used in accordance with this label.

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Resistance Management

Centric belongs to the neonicotinoid class of chemistry, which is not known to be cross-resistant to any other class of insecticide. However, insect pests are known to develop resistance to products used repeatedly. Because resistance development cannot be predicted, the use of this product should conform to sound resistance management strategies established for the crop and use area. The following label restrictions must be followed to reduce the chance of resistance development to Centric. Novartis encourages responsible product stewardship to insure effective long-term control of the insect pests on this label.

1) Do not make multiple applications of Centric to successive generations of the same pest in a season. Instead, rotate to another insecticide class. Multiple applications of Centric may be made to the same generation of a pest if needed.

2) During a crop season, alternate the use of Centric with products from different chemical classes.

3) It is recommended that the highest labeled rates of Centric be applied to control targeted pests.

Application Procedures and Spray Equipment

Ground Application

Spray nozzles should be selected which will provide accurate and uniform spray deposition. Use spray nozzles that provide medium-sized droplets and reduce drift. To help insure accuracy, calibrate sprayer before each use. For information on spray equipment and calibration, consult nozzle manufacturers and / or State Extension Service specialists.

Apply Centric using sufficient water volume to provide thorough and uniform coverage. In situations where a dense canopy exists and/or pest pressure is high, use greater water volumes. The use of a spray adjuvant may increase spray coverage but is not required. Avoid making applications under conditions where uniform coverage cannot be obtained or where excessive spray drift may occur. Avoid spray overlap.

Precautions: 1) When using water volumes of 5-10 gallons, fine-sized droplets may be used to improve spray coverage. 2) Select nozzles which produce the desired droplet sizes at the normal rated pressure range. 3) When spraying fine-sized droplets, carefully check *all* nozzles for flow and calibrate the sprayer. 4) The sprayer should travel at a uniform speed across the field. 5) Monitor environmental conditions and follow **Recommendations to Avoid Spray Drift** carefully.

Aerial Application:

Apply Centric in water, using a minimum spray volume of 5 gallons per acre. Increase spray volume where practical to improve coverage. Avoid making application under conditions where uniform coverage cannot be obtained or where excessive spray drift may occur. Avoid spray overlap.

Recommendations to Avoid Spray Drift

As with all crop protection products, it is important to avoid off-target movement. Do not allow spray to drift onto adjacent land, crops or aquatic areas. Follow these recommendations to avoid spray drift:

- Make ground applications when wind velocity favors on-target product deposition (Approximately 3 to 10 mph). Do not apply when wind velocity exceeds 10mph. Avoid applications when wind gusts approach 10mph.

- Risk of exposure to sensitive aquatic areas can be reduced by avoiding applications when wind direction is toward the aquatic area.

- Do not cultivate or plant crops within 25 feet of the aquatic area as to allow growth of a vegetative filter strip.

- Do not make aerial applications during temperature inversions. Inversions are characterized by stable air and increasing temperatures with increased height above the ground. Mist or fog may indicate the presence of an inversion in humid areas. The applicator may detect the presence of an inversion by producing smoke and observing a smoke layer near the ground surface.

- Use the largest droplet size consistent with good pest control. Small droplets are more prone to spray drift, and can be minimized by appropriate nozzle selection, by orienting nozzles away from the air stream as much as possible, and by avoiding excessive spray boom pressure.

- Apply as close to target plants as practical to obtain a good spray pattern for adequate coverage. Applications more than 10 ft above the crop canopy should be avoided.

- For aerial applications, the spray boom should be mounted on the aircraft so as to minimize drift caused by wing tip vortices. The minimum practical boom length should be used and must not exceed 75% of wing span or rotor diameter.

Mixing Procedures:

Prepare no more spray mixture than is needed for the immediate operation. Thoroughly clean spray equipment before using this product. Vigorous agitation is necessary for proper dispersal of the product. Maintain maximum agitation throughout the spraying operation. Do not let the spray mixture stand overnight in the spray tank. Flush the spray equipment thoroughly following each use and apply the rinsate to a previously treated area. Keep product container tightly closed when not in use.

Centric Alone: Add 1/2 of the required amount of water to the mix tank. With the agitator running, add the desired amount of Centric to the tank. Continue agitation while adding the remainder of the water. Begin application of the solution after Centric has completely dispersed into the mix water. Maintain agitation until all of the mixture has been applied.

Centric + Tank Mixtures: Add 1/2 of the required amount of water to the mix tank. Start the agitator running before adding any tank mix partners. In general, tank mix partners should be added in this order: products packaged in water-soluble packaging, wettable powders, wettable granules (dry flowables) such as Centric, liquid flowables, liquids, emulsifiable concentrates and surfactants / adjuvants. Always allow each tank mix partner to become fully dispersed before adding the next product. Provide sufficient agitation while adding the remainder of the water. Maintain agitation until all the mixture has been applied.

Note: When using Centric in tank mixtures, all products in water-soluble packaging should be added to the tank before any other tank mix partner, including Centric . Allow the water-soluble packaging to completely dissolve and the product(s) to completely disperse before adding any other tank mix partner to the tank.

If using Centric in a tank mixture, observe all directions for use, crop/sites, use rates, dilution ratios, precautions, and limitations that appear on the tank mix product label. No label dosage rate should be exceeded, and the most restrictive label precautions and limitations should be followed. This product should not be mixed with any product that prohibits such mixing. Tank mixtures or other applications of

products referenced on this label are permitted only in those states in which the referenced products are labeled.

Compatibility: Centric is compatible with most commonly used pesticides, crop oils, adjuvants, and nutritional sprays. However, since it is not possible to test all possible mixtures, the user should pre-test to assure the physical compatibility and lack of phytotoxic effect of any proposed mixtures with Centric. To determine the physical compatibility of Centric with other products, use a jar test, as described below.

Using a quart jar, add the proportionate amounts of the products to 1 qt. of water. Add wettable powders and water-dispersible granular products first, then liquid flowables, and emulsifiable concentrates last. After thoroughly mixing, let stand for at least 5 minutes. If the combination remains mixed or can be remixed readily, it is physically compatible. Once compatibility has been proven, use the same procedure for adding required ingredients to the spray tank.

The crop safety of all potential tank mixes on all crops has not been tested. Before applying any tank mixture not specifically recommended on this label, the safety to the target crop should be confirmed.

RECOMMENDED APPLICATIONS

CROP	PEST	RATE PER ACRE PER APPLICATION	REMARKS
COTTON	Cotton aphid Tarnished plant bugs (*Lygus lineolaris*)	3.0 oz/A	Apply before pests reach damaging levels. Scout fields and treat again if populations rebuild to potentially damaging levels. **Tarnished plant bugs**: Control may require the use of two applications.
Remarks: Do not exceed a total of 6.0 oz of Centric per acre per crop. Allow at least 14 days between applications. Do not apply closer than 21 days before harvest. Use sufficient water volume to ensure thorough coverage of foliage. Do not use less than 10 GPA for ground applications and 5 GPA for aerial applications			

Rotational Restrictions

Treated areas may be replanted immediately following harvest, or as soon as practical following the last application, with any crop listed on this label or to cucurbit, fruiting, tuberous & corm and leafy vegetables, cole crops, tobacco, sorghum, wheat, barley, and canola. Any cover crop planted for erosion control or soil improvement may be planted as soon as practical following the last application. However, the cover crop may not be grazed or harvested for food or feed. For all other crops, a 120 - day plant-back interval must be observed.

Storage and Disposal

Storage

Store in a cool dry place.

Pesticide Disposal

Do not contaminate water, food, or feed by storage or disposal. Pesticide wastes may be toxic. Improper disposal of unused pesticide, spray mixture, or rinse water is a violation of federal law. If these wastes cannot be used according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance in proper disposal methods.

Container Disposal

Triple rinse container. Then offer for recycling or reconditioning, or puncture and dispose of using one of the following methods: 1) depositing in a sanitary landfill,
2) incineration, or, 3) burning, if allowed by state and local ordinances. Stay out of smoke from burning containers.

For minor spills, leaks, etc., follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup, procedures and disposal of wastes. In the event of a major spill, fire, or other emergency call 1-800-888-8372, day or night.

Precautionary Statements

Hazards to Humans and Domestic Animals

Keep Out of Reach of Children

CAUTION

Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling.

Statement of Practical Treatment

If in eyes: Flush eyes with plenty of water. Get medical attention if irritation persists.

If on skin: Wash with plenty of soap and water. Get medical attention if irritation persists.

Note to Physician: If ingested, induce emesis or lavage stomach. Treat symptomatically.

Personal Protection Equipment
Applicators and other handlers must wear:

- Long-sleeved shirt and long pants

- Waterproof gloves
- Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

Engineering Control Statements

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Environmental Hazards

Do not apply directly to water, or to areas where surface water is present, or to inter-tidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash waters.

Physical or Chemical Hazards

Do not use, pour, spill or store near heat or open flame.

Centric™ trademark of Novartis
U.S. Patent No.

Novartis Crop Protection, Inc.
Greensboro, North Carolina 27419

NCP Product ID. (To Be Assigned)

File: MS / Centric Section 18 Label – MS – 03-13-00.doc

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07/OPP#181077

Bayer

Agriculture Division

Crop Protection Products

Bayer Corporation
8400 Hawthorn Road
P.O. Box 4913
Kansas City, MO 64120-0013
Phone: 816 242-2000

May 30, 2000

Mr. Stephen Schaible
Registration Division (7505C)
Office of Pesticide Programs
Environmental Protection Agency
Ariel Rios Bldg, 1200 Pennsylvania Ave. NW
Washington, DC 20460

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SUBJECT: ***Notice of Specific Exemption Request for Use of Centric on Cotton Docket No. OPP-181077***

Dear Mr. Schaible:

It is our understanding that U.S. EPA is considering an Emergency Exemption for the use of Centric (active ingredient thiamethoxam) to control aphids on cotton.

Bayer Corporation is unclear of the justification for this request. According to 40 CFR §166.20(a)(4), the application should contain a "detailed explanation of why the pesticide(s) currently registered... is not effective to the degree needed to control the emergency (if the applicant states that an available registered pesticide is ineffective for the given situation)." The statement must be supported by field data, or if such data are unavailable, by qualified experts.

As detailed in the notice, aphids are initially controlled with registered alternatives such as dicrotophos, endosulfan, methomyl, and imidacloprid. The comments contained in this response pertain solely to imidacloprid and not to the other registered alternatives.

Imidacloprid is the active ingredient in Provado 1.6 Flowable Insecticide (EPA Reg. No. 3125-457), initially registered by U.S. EPA in 1994, for control of aphids on cotton, among other registered uses. Imidacloprid belongs to the class of compounds known as neonicotinyls, as does thiamethoxam. Both compounds have the same mode of action and essentially the same spectrum of activity. Imidacloprid is extremely efficacious against aphids; thiamethoxam has similar and comparable activity.

We are not aware of any data showing statistically significant differences for control of aphids using thiamethoxam as compared to imidacloprid. On the contrary, data from many different trials conducted in different regions of the country directly comparing Provado and thiamethoxam (both at the same rate) show similar levels of control (summary table enclosed). When the percent control is averaged over different treatment intervals, Provado and thiamethoxam are comparable at the earlier intervals (2 -3 days, 4 - 7 days, and 10 - 15 days). Additionally, Provado appears to have slightly more residual control at the later intervals (21+ days) than does thiamethoxam, at the same rate (0.047 lb AI/A)

Therefore, since Provado has slightly more residual control than does thiamethoxam, the justification to use thiamethoxam because populations of aphids resurge rapidly following application of currently registered products is not a sufficient argument for granting this emergency exemption. Further, since the levels and lengths of control are similar for Provado and thiamethoxam, the argument that the yield losses would be decreased using thiamethoxam are unfounded.

To summarize, Bayer Corporation disagrees that there is sufficient justification to allow the Agency to grant this emergency exemption. Our position is supported by the following facts:

- Provado 1.6 Flowable is currently registered for this use (control of aphids on cotton),
- imidacloprid and thiamethoxam belong to the same class of chemistry and have the same mode of action, and
- imidacloprid and thiamethoxam have comparable levels of control (at the same rates) at 2 to 3 days following application, up to 10 to15 days following application.

Therefore, we respectfully request the Agency deny this request, as the required criteria for justifications of an emergency exemption have not been met.

Yours very truly,

BAYER CORPORATION
AGRICULTURE DIVISION

Karen S. Cain
Manager, Insecticide Registrations and State Regulatory Affairs
Research and Development Department

Enclosures

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Control of Cotton Aphid with Provado 1.6F vs. Thiamethoxam and Competitors

		%Control of APHIGO at DAT					
Trial #	State	DAT	Provado (0.047)	Thiamethoxam (0.047)	Fulfill	Furadan	Bidrin	Leverage
355-99-00012	LA	2	88	94	49	97		
355-99-00026	LA	3	71	83	52	85		
356-99-00017	AL	3	100	100	95			
457-99-00053	CA	3	46	23				67
459-99-00008	TX	3	85	98	93			
BMS-98-00030	MS	3	86	95			96	
BMS-98-00027	MS	3	55				87	79
BMS-99-00039	MS	3	80					59
Average % Control			79.3	82.2				
Knockdown			86.0	vs.Fulfill	72.3			
			79.5	vs. Furadan		91.0		
			70.5	vs. Bidrin			91.5	
			60.3	vs. Leverage				68.3
354-99-00012	AR	4	89	89				
VBL-98-00214	FL	5	94	98			88	
354-99-00012	AR	6	88	97				
BMS-96-00007	MS	6	78					74
BMS-96-0005	MS	6	80					81
355-99-00012	LA	7	70	91	69	72		
355-99-00026	LA	7	56	76	74	82		
457-99-00053	CA	7	76	42				73
459-99-00008	TX	7	84	97	93			
BMS-98-00030	MS	7	69	98			96	
FCA-98-00034	CA	7	94	90				
FCA-98-00035	CA	7	97	97				
FCA-99-00021	CA	7	95	97	88			
TGA-99-00339	GA	7	74	65			82	
456-99-00003	TX	7	83		71	90	76	90
BMS-98-00027	MS	7	39				85	48
BMS-99-00039	MS	7	74					63
FCA-97-00014	CA	7	66			43		
Average% Control			82.2	86.4				
Intermediate			77.6	vs.Fulfill	79.0			
			68.8	vs. Furadan		71.8		
			71.8	vs. Bidrin			85.4	
			71.7	vs. Leverage				71.5

Control of Cotton Aphid with Provado 1.6F vs. Thiamethoxam and Competitors

Trial #	State	DAT	%Control of APHIGO at DAT Provado (0.047)	Thiamethoxam (0.047)	Fulfill	Furadan	Bidrin	Leverage
456-96-00001	CA	10	76			91		
456-98-00011	TX	10	37			57		31
VBL-98-00214	FL	11	94	94			93	
355-99-00012	LA	14	70	89	0	75		
FCA-98-00034	CA	14	89	89				
FCA-98-00035	CA	14	91	91				
FCA-99-00021	CA	14	60	63	76			
FCA-97-00014	CA	14	68			90		
457-99-00053	CA	15	38	11				25
456-98-00015	TX	15	68			85		41
Average % Control**			73.7	72.8				
Residual			63.8	vs. Bidrin		79.6		
			47.7	vs. Leverage				32.3
FCA-98-00034	CA	21	86	70				
FCA-98-00035	CA	21	77	66				
FCA-99-00021	CA	21	58	61	75			
VBL-98-00214	FL	23	30	20			0	
Average %control**			62.75	54.25				
Residual								

****Averages calculated on direct comparisons between compounds in the same trials only.**

Control of Cotton Aphid with Provado 1.6F vs. Thiamethoxam and Competitors

Trial #	State	DAT	%Control of APHIGO at DAT Rate listed is in lb ai/acre Provado (0.047)	Thiamethoxam (0.047)	Fulfill	Furadan	Bidrin	Leverage	Source Data
354-99-00012	AR	4	89	89					Field Dev.
		6	88	97					
355-99-00012	LA	2	88	94	49	97			Leonard (LSU)
		7	70	91	69	72			
		14	70	89	0	75			
355-99-00026	LA	3	71	83	52	85			Leonard (LSU)
		7	56	76	74	82			
356-99-00017	AL	3	100	100	95				Field Dev.
457-99-00053	CA	3	46	23				67	T. Prescott (grower)
		7	76	42				73	
		15	38	11				25	
459-99-00008	TX	3	85	98	93				Hopkins (Hopkins Agric.Services)
		7	84	97	93				
BMS-98-00030	MS	3	86	95			96		Bayer Farm Benoit
		7	69	98			96		
FCA-98-00034	CA	7	94	90					Bayer Farm Fresno
		14	89	89					
		21	86	70					
FCA-98-00035	CA	7	97	97					Bayer Farm Fresno
		14	91	91					
		21	77	66					
FCA-99-00021	CA	7	95	97	88				Bayer Farm Fresno
		14	60	63	76				
		21	58	61	75				
TGA-99-00339	GA	7	74	65			82		Bayer Farm Tifton
VBL-98-00214	FL	5	94	98			88		Bayer Farm Vero Beach
		11	94	94			93		
		23	30	20			0		
456-96-00001	OK	10	76			91			Field Dev.
456-98-00011	TX	10	37			57		31	Field Dev.
456-98-00015	TX	15	68			85		41	Field Dev.
456-99-00003	TX	7	83		71	90	76	90	Swart at Texas A&M
BMS-96-00007	MS	6	78					74	Bayer Farm Benoit
BMS-96-0005	MS	6	80					81	Bayer Farm Benoit
BMS-98-00027	MS	3	55				87	79	Bayer Farm Benoit
		7	39				85	48	
BMS-99-00039	MS	3	80					59	Bayer Farm Benoit
		7	74					63	
FCA-97-00014	CA	7	66			43			Bayer Farm Fresno
		14	68			90			
Average %control**			77.0	78.0					
Over all DATs			64.9	vs.Fulfill	69.6				
			68.5	vs. Furadan		78.8			
			69.3	vs. Bidrin			78.1		
			62.8	vs. Leverage				60.9	

****Averages calculated on direct comparisons between compounds in the same trials only.**

08/08/#181077

mail

(4PP)

June 5, 2000

Mr. Stephen Schaible
Registration Division (7505C)
OFFICE OF PESTICIDE PROGRAMS
ENVIRONMENTAL PROTECTION AGENCY
Ariel Rios Building, 1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460.

Re: Docket Control Number OPP-181077

Dear Mr. Schaible:

We represent Bayer AG ("Bayer") in connection with the state of Mississippi's request for a specific emergency exemption to use the thiamethoxam-based product Centric to treat an alleged increased risk of cotton aphid (Aphid gossypii) in Mississippi. Bayer submits this letter to respectfully urge this Agency not to grant the requested exemption.

Under 40 C.F.R. § 166:

A specific exemption may be authorized in an emergency condition to avert:

(1) A significant economic loss; or
(2) A significant risk to:
  (i) Endangered species,
  (ii) Threatened species,
  (iii) Beneficial organisms, or
  (iv) The environment.

Id. § 166.2(a). An emergency condition will exist if an applicant demonstrates that (1) "[n]o effective pesticides are available under the Act that have labeled uses registered for control of the pest under the conditions of the emergency;"(2) "[n]o economically or environmentally feasible

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[1/]Other situations, none of which are relevant to Mississippi's application, can also justify the granting of an exemption. *See* § 166.3(d)(3)(i)-(iii) & (iv)(B).

alternative practices which provide adequate control are available;" and (3) "significant economic loss" will occur "due to an outbreak or an expected outbreak of a pest."[1/] *Id.* § 166.3(d). Here, no emergency exemption should be granted to Mississippi because Mississippi has not demonstrated that (1) no registered pesticides effectively control the cotton aphid; and (2) any significant economic losses will occur as a result of any current or expected outbreak of cotton aphid. In fact, Provado (Imidacloprid), a pesticide manufactured by Bayer, is registered for use on, and effectively combats, cotton aphids, and will prevent any significant economic losses that might otherwise occur from cotton aphid infestation.

(1) *Mississippi Has Not Demonstrated That Provado Is Ineffective*

To secure a specific emergency exemption, Mississippi must establish that "[n]o effective pesticides are available under the Act that have labeled uses registered for control of the pest under the conditions of the emergency." *Id.* § 166.3(d)(1). Mississippi contends in general terms that an exemption for Centric is warranted because existing registered pesticides, including presumably Provado, provide inconsistent control of the cotton aphid.[2/] In its application, however, Mississippi cites only a summary of two small scale trials conducted in Mississippi and Louisiana in which Centric was compared to Provado in 1999. To obtain an exemption, Mississippi must explain why Provado is ineffective and support its assertion with "field data" or statements from "qualified agricultural experts, extension personnel, university personnel or other persons similarly qualified in the field of pest control." See 40 C.F.R. § 166.20 (a)(4)(i). The two trials cited by Mississippi hardly afford this Agency the opportunity to make an informed evaluation about Centric's comparative effectiveness, and are insufficient to justify the granting of a specific emergency exemption.

(2) *Mississippi Has Not Demonstrated Any Potential Economic Loss*

To obtain a specific emergency exemption, Mississippi must also explain the "anticipated significant economic loss" that will occur if the requested exemption is not approved, and provide " data and other information supporting the discussion." 40 C.F.R. § 166.20(b)(4). In its

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[1/]Other situations, none of which are relevant to Mississippi's application, can also justify the granting of an exemption. *See* § 166.3(d)(3)(i)-(iii) & (iv)(B).

[2/]Mississippi asserts that existing insecticides for "cotton aphid control are variable in effectiveness to the extent that agricultural consultants and cotton producers consider them to be unreliable." Application at II., ¶ 3, and that "numerous reports received from producers and consultants in 1995 indicated inconsistent control with all recommended products in actual field use and populations rebounding rapidly following treatment," *id.* at V.

application, Mississippi suggests that the estimated yield loss of cotton from using currently available products will be as high as fifty pounds per acre if the requested exemption is not approved, and that using Centric would reduce the yield loss to ten pounds per acre. In neither case, however, does Mississippi provide a source or calculation to illustrate how it arrived at the projected ten and fifty pounds per acre losses. The calculated yield loss figure is the only variable affecting Mississippi's calculation of gross revenues, and therefore is the most critical factor affecting Mississippi's allegations of significant economic loss. In the absence of such information, it is impossible to determine the accuracy of Mississippi's projected yield losses. Once again, Mississippi has failed to provide the requisite supporting information, and its application must be denied.

Conclusion

Since its introduction, Provado has proven to be one of the best insecticides for controlling cotton aphids in the southeastern United States, including Mississippi. Mississippi has not met its burden of demonstrating that Provado is ineffective in controlling cotton aphids, nor has it even established that any significant economic losses will occur as a result of any current or expected outbreak of cotton aphid. Accordingly, Bayer respectfully urges that Mississippi's application for a specific emergency exemption be denied.

Very truly yours,

Robert J. Koch

RJK/tgs

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Rkoch@fulbright.com on 06/05/2000 09:55:17 PM

To: Opp-docket@epamail.epa.gov
cc:
Subject: OPP-181077

If any difficulties arise in viewing the attached, please contact me by e-mail or telephone at 202 662 4765.

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